UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,530	02/16/2005	Cindy Castado	B45292	7712

25308 7590 10/19/2005

DECHERT
ATTN: ALLEN BLOOM, ESQ
4000 BELL ATLANTIC TOWER
1717 ARCH STREET
PHILADELPHIA, PA 19103

EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,530	CASTADO ET AL.	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

All claims embrace a very large number of permutations of sequences for search and examination. Even if one specific SEQ ID No. is selected from claim 1, the examiner have to search for all of the sequences which have a 85% identity, which will constitute undue burden.

Applicant is required to select one combination of sequences from an isolated polypeptide or polynucleotide from (i) as recited in claim 31 and one labeled probe from (ii) as recited in claim 43, from the following sequences:

(i) a single disclosed specie from a genus comprising the following variants:
SEQ ID No: 2, 4, 6, 8, 10,12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58,60, 62, 64, 66, 68, 70 or 72 as recited in claim 31, and

(ii) one DNA sequence used to screen an appropriate library to obtain the SEQ ID Nos. recited above (i) from the genus comprising the following variants:
SEQ ID NO: 1, 3, 5, 7, 9, 1 1, 13, 15, 17, 19, 21,23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71 or 73 as recited in claim 43.

Each particular permutation is distinct from one another because of the following reasons. The specification fails to disclose that all of the polynucleotides SEQ ID Nos: 1-73 share a common property or activity. While each sequence may serve as a probe to isolated its own respective full length DNA, due to lack of homology between SEQ Nos.: 2, 4, 6, 8, 10,12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58,60, 62, 64, 66, 68, 70 or 72, a probe derived from SEQ ID NO: 1 cannot be used to isolated SEQ ID Nos: 4, 6, 8, 10,12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58,60, 62, 64, 66, 68, 70 or 72.

Moreover, since the polynucleotide fragments are not homologous to each other, they fail to share a common structure i.e., a significant structural element (see, Table 1 in the specification for description of each claimed polynucleotide). The lack of capsule cannot be considered a significant structural element; since it is shared by all nucleic acid isolates encoding *Haemophilus influenzae* variants. Therefore the 36 polynucleotide molecules of (i) and 37 polynucleotieds molecules of (ii) do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that polynucleotide fragments encoding for *H. influenzae* isolates that fail to agglutinate with antisera raised against one of the six serotypes corresponding to the polysaccharide capsule of H. *influenzae* is not sufficient to meet the criteria for unity of Invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotides molecules claimed does not meet the requirement of unity *(a priori)*.

Further, due to the lack of computer resources at the USPTO, and the large number of sequences requested to be examined, searching for these sequences will impose an enormous burden in the examiner if more than one specific permutation is elected.

Should a group drawn to a combination of two sequences comprising one specific ID No. from (i) and one specific labeled probe from (ii) be elected, restriction is further required under 35 U.S.C. 121 and 372.

Group I, claims 31-43, 44, 45, 46, 47, 48, 49, 50 and 57 drawn to an isolated polynucleotide and derivatives thereof from one of the selected combinations coding for a non typeable *H. influenzae,* a method for a expressing a polynucleotyde, a genetically modified host cell, a method for expressing a polypeptide, and an immunogenic composition.

Group II, claim 51 and 54, drawn to an antibody immunospecific for a member of a non typeable *H. influenzae* or derivatives thereof from one of the selected combinations and a therapeutic composition comprising said antibody.

Group III, claims, 52 and 53 drawn to a method of diagnosis of non typeable *H. influenzae* or derivatives thereof from one of the selected combinations.

Group IV, claim 54, drawn to a therapeutic composition useful in treating humans with a non typeable *H. influenzae* from one of the selected combinations.

Group V, claim 55 and 56, drawn to a method generating an immunoresponse comprising administering an immunogenic composition of a peptide from one of the selected combinations.

Group VI, claim 58 and 59, drawn to a Lipo-oligosaccharide and a method of generating a Lipo-oligosaccharide *in vitro.*

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-VI do no relate to a single general inventive concept under PCT 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the inventions listed as Groups I-VI are drawn to multiple distinct processes of use and multiple distinct products that do not share the same inventive concept. The claimed inventions of Groups I-VI recite distinct materials and/or method, and thus have their own special technical features, e.g., an isolated polynucleotide, a genetically modified host cell, a method for producing a polynucleotide, a method for producing a polypeptide expressing *H. influenzae* (Group I), an antibody (Group II), and a a Lipo-oligosaccharide and method of generation (Group VI).

Each invention is directed to distinct goals, which comprises a DNA encoding a non typeable *H. influenzae* or derivatives thereof, a non typeable *H. influenzae* or derivatives thereof, a host transformed with a nucleic acid encoding a non typeable *H. influenzae* or derivatives

thereof or different methods to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I to VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclose species for each of the groups above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are not generic claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the

patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nguyen Dave can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER